

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
50-R-0006

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT) 16-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

University of Delaware
Office of Laboratory Animal Medicine
220 Wolf Hall
Newark, DE 19716
Status: Active

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

020 Wolf Hall/McKinley Hall

175 McKinley Lab

126 Worrilow Hall

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	6	0	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Goats	0	11	0	0	11
13. Other Animals					
White Tailed Deer	0	0	16	0	16

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE

(Print)

DATE SIGNED

4/15/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
50-R-0011

CUSTOMER NO.
719

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

ANALYTICAL BIOLOGICAL SERVICES INC.
CORNELL BUSINESS PARK 701-4
WILMINGTON, DE 19801
(302) 654-4492

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		150			150
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

OFFICIAL (Type or Print)

DATE SIGNED

12/10/01

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE1. REGISTRATION NO.
50-R-0013FORM APPROVED
OMB NO. 0578-0036ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA
include Zip Code)
Strategic Diagnostics, Inc.
128 Sandy Dr
E328/B31
Newark, DE 19713
Status: Active

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

52 Anderson Road, Windham, Maine

26578 Old Julian Hwy, Ramona, CA

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	3	100	0	0	100
7. Hamsters	0	14	0	0	14
8. Rabbits	578	14,609	50	0	14,659
9. Non-human Primates					
10. Sheep	5	75	0	0	75
11. Pigs					
12. Other Farm Animals					
Goats	60	557	39	0	596
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(Certify that the above is true, correct, and complete (7 U.S.C. Section 2143))

SIGNATURE OF A.F.A. OR INSTITUTIONAL OFFICIAL

DATE SIGNED

12/03/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
50-R-0009

CUSTOMER NO.
47

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

NEMOURS FOUNDATION, THE
1600 ROCKLAND RD
WILMINGTON, DE 19899

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

LIFE SCIENCES CENTER
WILMINGTON, DE 19803

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	1		10		10
9. Non-Human Primates					
10. Sheep					
11. Pigs			15		15
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

DATE SIGNED

10/09/2001

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
50-R-0001

CUSTOMER NO.
41

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

E. I. DUPONT DENEMOURS & COMPANY, INC.
ELKTON ROAD
P.O. BOX 50
NEWARK, DE 19714
(302) 366-6318

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.) Haskell Laboratory, Building 1

FACILITY LOCATIONS(sites)

See Attached Listing

Haskell Laboratory Building 1

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs		2	1	0	3
7. Hamsters		0	178	0	178
8. Rabbits		575	0	32	607
9. Non-Human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I hereby certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/20/01

which is obsolete

(AUG 91)

PART 1 - HEADQUARTERS



11-20-2001 RCVD

DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

November 13, 2001

Elizabeth Goldentyer, DVM
USDA, APHIS, REAC
Eastern Regional Office
920 Main Campus Drive
Raleigh, NC 27606

Dear Dr. Goldentyer:

To address the issue of the category E animals in the USDA annual report of the DuPont Haskell Laboratory for Health and Environmental Sciences (50-R-0001), I am providing a list of five types of skin irritation studies and four types of eye irritation studies which were conducted in rabbits to meet the criteria of various regulatory agencies. All study protocols and SOP's were reviewed and approved by the Haskell Laboratory's Institutional Animal Care and Use Committee (IACUC).

Skin Irritation Studies

Thirteen (13) rabbits that were used in one of the following tests experienced signs that were considered to fall into category E. These studies comply with or are based on (screening studies) test guidelines OPPTS 870.2500 (1998) and OECD 404 (1992).

1. Skin Irritation Study in Rabbits – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).
2. Skin Irritation Study Under Potential Use Conditions – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).
3. Acute Dermal Irritation/Corrosion Study – This study is conducted for the registration of agricultural products with the Organization for Economic Cooperation and Development (OECD) and European Economic Community (EEC). The Acute Dermal Irritation/Corrosion Test is also conducted to aid in determining a Workplace Hazardous Material Identification System (WHMIS) rating for Canada and a Hazardous Material Identification System (HMIS) rating for the United States.
4. Skin Absorption Approximate Lethal Dose Study – This study is performed for safety assessment and to determine a packaging class for the transportation of chemicals.

Eye Irritation Studies

Fifteen (15) rabbits that were used in one of the following tests experienced signs that were considered to fall into category E. These studies comply with or are based on (screening studies) test guidelines OPPTS 870.2400 (1998) and OECD 405 (1987).

1. Eye Irritation Study – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).
2. Primary Eye Irritation Study – This study is conducted for the registration of agricultural products with EPA FIFRA.
3. Acute Eye Irritation/Corrosion Study – This study is conducted for the registration of agricultural products with the Organization for Economic Cooperation and Development (OECD) and European Economic Community (EEC).
4. Eye Irritation Screen – The purpose of this study is to supply safety assessment information for Discovery compounds.

An additional four (4) rabbits used in IACUC approved developmental toxicity studies were found dead or were euthanatized because of oral gavage trauma. The amount and degree of pain and distress, if any, could not be determined. These studies comply with or are based on (range-finding studies) test guidelines OPPTS 870.3700, OECD 414 (2001) or OECD 421 (1995).

Testing for registration of crop protection chemicals is required under CFR 40 Part 158. Other testing is done for product stewardship purposes, for the reasons cited above.

The IACUC approved the conduct of these studies without the use of anesthetics, analgesics or tranquilizing drugs because the use of such drugs could adversely influence the experimental compound's effect on the animal or alter the animal's reaction to the experimental compound, resulting in invalid interpretation of the clinical signs by the scientists. Test guidelines (OPPTS) for these study types do not allow for the use of anesthetics, analgesics, or tranquilizing drugs, other than allowing use of local anesthetics in eye irritation studies where extreme pain is expected. Most tested substances are novel materials for which there is little or no information available upon which to predict the response. Test substances are not tested if it is expected they will produce corrosion or severe irritation (e.g., based on pH). They are tested in step-wise fashion (one rabbit first, then two more if the first does not display severe response) if the test substance may be expected to produce a severe response, based on data from similar materials.

DuPont actively supports research programs to develop scientifically acceptable refinements and alternatives to animal testing. We do use a commercially available in vitro system (Corrositex®) as a screen. We have also developed and validated the mouse local lymph node assay, which is used as a replacement for guinea pig dermal sensitization screening, where permitted by regulatory agencies. This assay is a refinement of the sensitization testing which involves much shorter exposures than the guinea pig assays. In those cases where the in vitro system provides sufficient information, no additional studies with animals are performed. At present, there are no validated alternatives that would completely replace animal tests which are required by national and international laws and regulations.

Also, please note that there were no exemptions or exceptions to any USDA regulations and standards to report for this year.

Sincerely,

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
50-R-0003

CUSTOMER NO.
27

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

11-27-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

INTERVET, INC.
405 STATE STREET
P.O. BOX 318
MILLSBORO, DE 19966
(302) 934-8051

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

See Attached Listing

Millsboro, DE

DeSoto, KS & Shawnee, KS

Dallas Center, IA

Worthington, MN & Rushmore, MN

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	32	514	70	37	621
5. Cats		809	396	22	1227
6. Guinea Pigs		1180	1811		2991
7. Hamsters		7038	70	7768	14896
8. Rabbits		616	1552		2168
9. Non-Human Primates					
10. Sheep					
11. Pigs		2189			2189
12. Other Farm Animals					
CATTLE		499	5		504
13. Other Animals					
HORSES	85				
GOATS		2			2

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

DECLARATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

Executive Officer or Legally Responsible Institutional official)

Verify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE

OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11-30-01

APHIS

(AUG 91)

1-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-003

2. Number 7768 of animals used in this study.

3. Species (common name) Hamsters of animals used in the study.

4. Explain the procedure producing pain and/or distress.

All Hamsters were used for testing as specified in 9CFR113.103 and 113.102. As stated death is the end point.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS CFR 113.103 and 113.102

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-003
2. Number 30 of animals used in this study.
3. Species (common name) Dogs of animals used in the study.
4. Explain the procedure producing pain and/or distress.

All 30 dogs were used for testing as specified in 9CFR 113.209
And as stated clinical signs and death are required to determine
efficacy when inoculated with rabies.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS CFR 113.209

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-003
2. Number 7 of animals used in this study.
3. Species (common name) Dogs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

9CFR mandates that vaccine efficacy is to be established by demonstrating the prevention or statistical reduction of clinical signs exhibited by vaccinated animals as compared to non-vaccinated control animals following challenge with a virulent isolate.

Clinical signs are used as bases for evaluating efficacy. Amelioration of pain due to challenge would prevent assessment of vaccine efficacy.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS CFR 113.305

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-003
2. Number 22 of animals used in this study.
3. Species (common name) Cats of animals used in the study.
4. Explain the procedure producing pain and/or distress.

All (22) cats were used to evaluate safety and efficacy of potential potential product candidates. Observations of clinical signs were required to evaluate product efficacy and use of drugs or other means to alleviate clinical signs would interfere with determination of efficacy, making product selection impossible. All animals were observed regularly and would have been treated or euthanized if the pain and distress was determined to adversely affect the overall welfare of the animals.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS CFR 113.71

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
50-R-0004

CUSTOMER NO.
42

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

ZENECA, INC. AstraZeneca Pharma,
P.O. BOX 15437
(1800 CONCORD PIKE)
WILMINGTON, DE 19850-5437
(302) 886-8053

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs		25			25
5. Cats					
6. Guinea Pigs		3,240	4,120	689	8,049
7. Hamsters					
8. Rabbits		190			190
9. Non-Human Primates		42			42
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Gerbil		71	2330	795	3,196
Ferret			152		152

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

(Type or Print)

DATE SIGNED

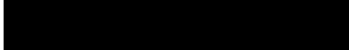
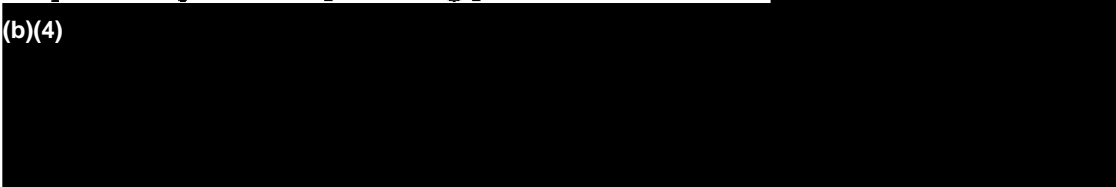
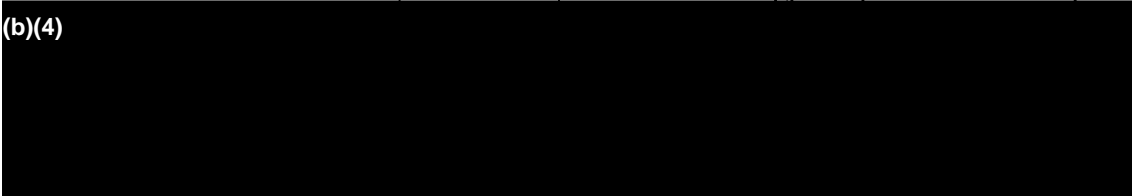
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PART 1 - HEADQUARTERS


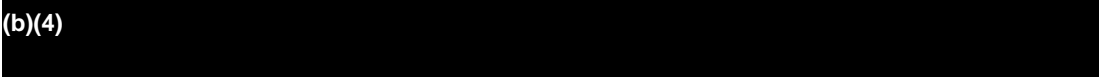
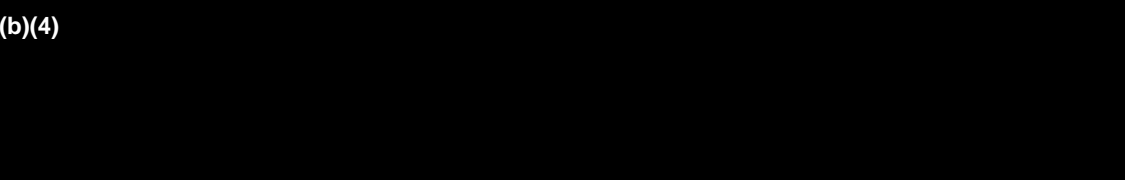
Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 440
3. **Species (common name) of animals used in this study:** Gerbil
4. **Explain the procedure producing pain and/or distress:** 
(b)(4) 
5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4) 
6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A

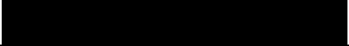
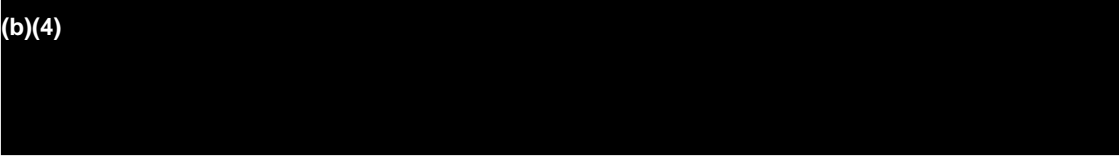

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1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 335
3. **Species (common name) of animals used in this study:** Gerbil
4. **Explain the procedure producing pain and/or distress:** 
(b)(4) 
5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4) 
6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A



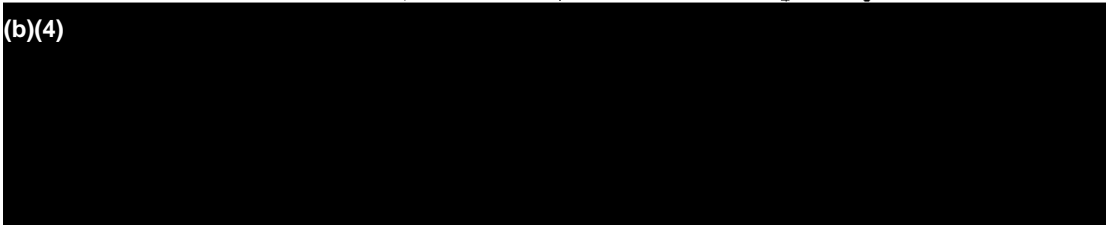
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1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 20
3. **Species (common name) of animals used in this study:** Gerbil
4. **Explain the procedure producing pain and/or distress:** 
(b)(4) 
5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4) 
6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A

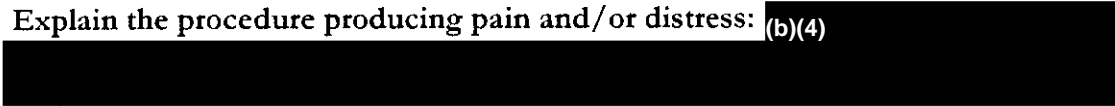

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1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 100
3. **Species (common name) of animals used in this study:** Guinea Pig
4. **Explain the procedure producing pain and/or distress:** 
(b)(4) 
5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4) 
6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A

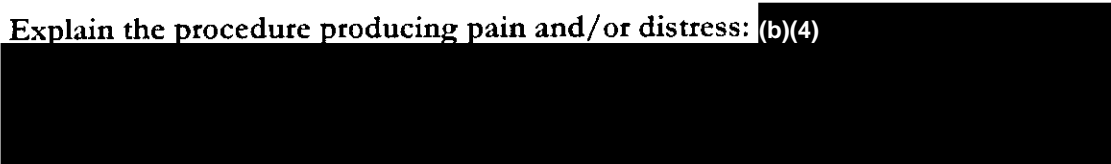
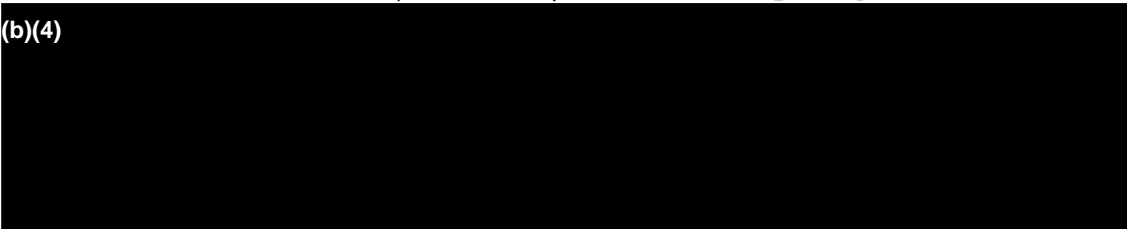
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1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 165
3. **Species (common name) of animals used in this study:** Guinea Pig
4. **Explain the procedure producing pain and/or distress:** (b)(4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A

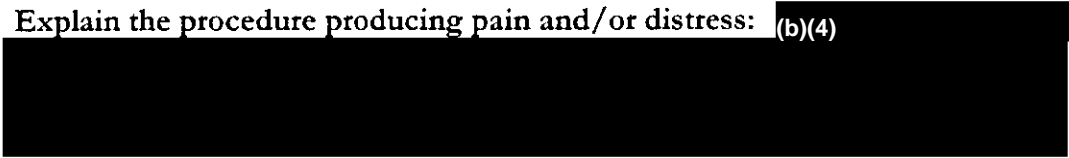
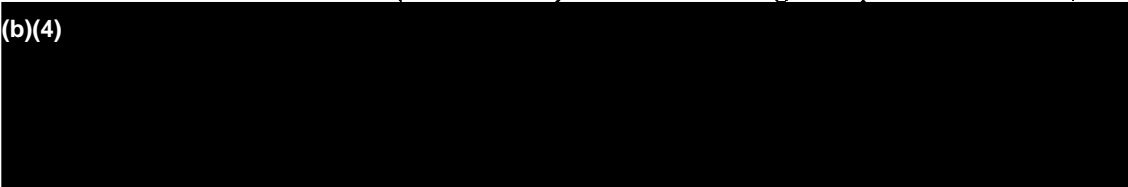
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1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 168
3. **Species (common name) of animals used in this study:** Guinea Pig
4. **Explain the procedure producing pain and/or distress:** (b)(4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A

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1. **Registration Number:** 50-R-0004
2. **Number of animals used in this study:** 256
3. **Species (common name) of animals used in this study:** Guinea Pig
4. **Explain the procedure producing pain and/or distress:** (b)(4)

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below.):**
(b)(4)

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):** N/A